RECEIVED AT DRUG SAFETY SURVEILLANCE
19-FEB-1998-0680

McNEIL CONSUMER PROD
FORT WASHINGTON

Page ____ of __

Individual Safety Report
3031735-3-00

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
Case 191 in confidence	40 yrs or Date of birth:	(X)female ( )male	unk lbs or kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- (X) death (mo/day/yr) unknown
- ( ) life-threatening
- (X) hospitalization - initial or prolonged
- ( ) disability
- ( ) congenital anomaly
- ( ) required intervention to prevent permanent impairment/damage
- ( ) other:

3. Date of event (mo/day/yr)	4. Date of this report (mo/day/yr)
unknown	02/06/98

5. Describe event or problem

Case # 191 received from the [redacted] case fatality data. See attached case report form provided by [redacted]

FEB 1 [illegible]

6. Relevant tests/laboratory data, including dates

See attached case report form provided by [redacted]

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

See attached case report form provided by [redacted]

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 TYLENOL Analgesic Unknown
#2

2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 8-10 TYLENOL/day, po	#1 approx 1 week
#2	#2

4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 unknown	#1 ( ) Yes ( ) No (X) N/A
#2	#2 ( ) Yes ( ) No ( ) N/A

6. Lot # (if known)	7. Exp. date (if known)	8. Event reappeared after reintroduction
#1 Unknown	#1 Unknown	#1 ( ) Yes ( ) No (X) N/A
#2	#2	#2 ( ) Yes ( ) No ( ) N/A

9. NDC # - for product problems only (if known)

- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

See attached case report form provided by [redacted]

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Products Company
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number: 215-233-7820

3. Report source (check all that apply)

- ( ) foreign
- ( ) study
- (x) literature
- ( ) consumer
- (x) health professional
- ( ) user facility
- ( ) company representative
- ( ) distributor
- ( ) other:

4. Date received by manufacturer (mo/day/yr): 01/30/98

5. (A) NDA # 17-552
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)

- ( ) 5-day (X) 15-day
- ( ) 10-day ( ) periodic
- (X) Initial ( ) follow-up #

8. Adverse event term(s)

OVERDOSE
LIVER FUNC ABNO
COAGULATION DIS
APNEA
HYPOGLYCEMIA
ACIDOSIS
KIDNEY FUNC ABN
DEATH

9. Mfr. report number: 0929510A

E. Initial reporter

1. Name, address & phone #

[redacted] MD
[redacted] Centers
Suite [redacted] Avenue
[redacted]

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
(X) Yes ( ) No	physician	( ) Yes ( ) No (X) Unk

FDA
Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

[redacted]TESS FATALITY: 1996 [redacted]

Case Number:	**191**
Age:	40 yrs
Substances:	Acetaminophen
Chronicity:	Chronic
Route:	Ingestion
Reason:	Int Unknown
Pre-Hospital Arrest?	No

40 yo female who was transported to the local ED by friends because of a change in her mental status. Apparently one week ago she had fallen and injured her chest wall and was taking 8-10 Tylenol per day plus ibuprofen and Orudis for pain for the past week. Her PMH was unremarkable. Her social history was remarkable for 3 alcoholic drinks 2-3x/week. In the ED the patient was confused and had a blood glucose of 20 which responded to 50 cc of D50W with clearing of her mental status. Her initial BP was 68 systolic which responded to fluids. Her initial labs showed a sodium 132 mmol/L, potassium 4.2 mmol/L, chloride 85 mmol/L, BUN 10 mg/dL, creatinine 2.6 mg/dL, glucose 36 mg/dL, AST >26000 U/L, INR >17, PTT 49.3 sec, acetaminophen 28 ug/ml, lactate 8.2 and ABG pH 7.38, pCO2 27 mmHg, pO2 67 mmHg, bicarbonate 13 mmol/L. Initial head CT was negative. The next morning following her admission IV NAC was started and because of a worsening mental status, increasing coagulopathy and worsening renal function she was transferred to the liver transplant unit. Less than 12 hours later she required innubation for a decreasing mental status and respiratory failure. She expired on hospital day 3. IV NAC was continued until she expired.